The Office Action

Claims 1-14, 16-33, and 35-38 are provisionally rejected for obviousness-type double patenting over claims 1-14, 31-48 and 50-69 of co-pending application Serial No. 09/804,925 and claims 1-17, 31-48, and 50-65 of co-pending application Serial No. 09/804,963.

Claims 1-38 are rejected as being obvious over U.S. Patent No. 6,265,509 to Müller ("Müller") alone or in view of U.S. Patent No. 6,162,844 to Lally et al. ("Lally").

Cited References

U.S. Patent No. 6,265,509 to Müller teaches mouldings formed from prepolymers (also known as macromers) containing a crosslinkable group and at least one unit containing a modifier. The prepolymers are based on starting polymers which have a polyhydroxy 1,2 or 1,3 diol structure. The crosslinkable groups are crosslinkable via "photocrosslinking, thermal crosslinking or 2+2 photocyclodimerization." (See column 12, lines 52-53.) The preferred method is photocrosslinking, which generally requires the use of a photoinitiator and the crosslinking is initiated by actinic or ionizing radiation. (See column 12, lines 54-60.)

As the Examiner points out, Müller teaches that various mouldings can be formed, such as "biomedical and ophthalmic mouldings, mouldings used in surgery, such as heart valves and artificial arteries, films and membranes". (See the Office Action, page 3.) Such mouldings are produced by introducing the prepolymer into a mould, crosslinking the prepolymer, and then removing the moulding from the mould. (See the Office Action page 4.)

U.S. Patent No. 6,162,844 to Lally et al. ("Lally") teaches a method of incorporating a reactive dye into a polymeric material. The polymer is formed from crosslinkable prepolymers, such as those described by Müller.

Analysis

Double Patenting Rejections

Applicant defers discussion of this issue until the claims of the present application have been allowed. If necessary, terminal disclaimer(s) will be submitted.

103 Rejection

The rejection of claims 1-38 over Müller alone or in view of Lally is respectfully traversed. Claims 2-4, 7, and 14-38 were cancelled. Claim 1 was amended and new claims 39 and 51 have been added. However, the subject matter of claims 1, 39, and 51 is not new but is simply original claims 16, 13, and 10 in independent form.

Claim 1 (original claim 16 in independent form) as amended specifies that the biomedical article is a microparticle.

Claim 39 (original claim 13 in independent form) specifies that the crosslinkable groups of the prepolymer are crosslinked via redox initiated free radical polymerization.

Claim 51 (original claim 10 in independent form) specifies that the article is biodegradable.

Claim 1

Neither Müller nor Lally teaches or suggests microparticles formed from macromers having a polymeric backbone comprising units having a 1,2-diol or 1,3-diol structure and at least two pendant chains bearing crosslinkable groups.

Both cited references teach that the macromers (prepolymers) can be used to make mouldings- devices formed by placing the macromers in a mould and crosslinking the macromers. The articles formed are shaped like the mould. See column 14, lines 50-64 of Müller.

> The novel prepolymers can be converted into mouldings, in particular contact lenses, in a manner known per so, for example by carrying out the crosslinking of novel prepolymers in a suitable contact-lens mould. The invention therefore furthermore relates to mouldings essentially comprising a novel crosslinked polymer. Further examples of novel mouldings, besides contact lenses, are biomedical mouldings and mouldings for specifically ophthalmic purposes, for example intraocular lenses, eye bandages, mouldings which can be used in surgery, such as heart valves, artificial arteries or the like, furthermore films and membranes, for example membranes for diffusion control, photostructurable films for information storage, and photoresist materials, for example membranes and mouldings for etch resists and screen printing resists.

Microparticles are not made using a moulding process. A mould is not used to shape the particles- they are "free formed" using a method such as suspension polymerization, for

example. See page 21-22 of the application for a description of possible methods for making microparticles from macromers.

Müller alone, or in combination with Lally, does not teach or suggest that the prepolymers taught therein can be used to make microparticles.

Claim 39

Neither Müller nor Lally teaches or suggests that the prepolymers are crosslinked via redox initiated free radical polymerization. Both teach that the crosslinkable groups are crosslinkable via "photocrosslinking, thermal crosslinking or 2+2 photocyclodimerization." (See Müller at column 12, lines 52-53.) The preferred method is photocrosslinking, which generally requires the use of a photoinitiator and the crosslinking is initiated by actinic or ionizing radiation. (See Müller at column 12, lines 54-60.) Photoinitiation requires the use of an outside influence- a radiation source. Initiation via redox chemistry on the other hand, does not require the use of an outside influence. The system can be self-contained, with the use of a two part system having one part containing the reductant and the other part containing the oxidant. The system can thus be used for applications where it is difficult or otherwise desirable to employ a light source.

Claim 51

Neither Müller nor Lally teaches or suggests a biodegradable medical article formed from macromers having a polymeric backbone comprising units having a 1,2-diol or 1,3-diol structure and at least two pendant chains bearing crosslinkable groups. The hydrogels formed from the macromers taught in the cited references are not degradable. Biodegradability is not mentioned as desirable or achievable.

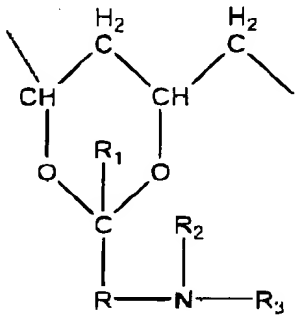
Claims As Amended Showing Amendments

1. (Once Amended) A [hydrogel biomedical article] microparticle formed from macromers having a polymeric backbone comprising units having a 1,2-diol or 1,3-diol structure and at least two pendant chains bearing crosslinkable groups.

Claims 2- 4 (Cancelled)

5. (Once Amended) The [hydrogel biomedical article] microparticle of claim 1, wherein the backbone polymer comprises poly(vinyl alcohol) (PVA) and copolymers thereof.

6. (Once Amended) The [hydrogel biomedical article] microparticle of claim 1, wherein the macromer has the formula:



in which R is a linear or branched C_1-C_8 alkylene or a linear or branched C_1-C_{12} alkane; R_1 is hydrogen, a C_1-C_6 alkyl, or a cycloalkyl; R_2 is hydrogen or a C_1-C_6 alkyl; and R_3 is an olefinically unsaturated electron attracting copolymerizable radical having up to 25 carbon atoms.

7. (Cancelled)

8. (Once Amended) The [hydrogel biomedical article] microparticle of claim 1, further comprising an active agent.

9. (Once Amended) The [hydrogel biomedical article] microparticle of claim 8, wherein the [hydrogel] microparticle releases the active agent over a period of time ranging from about 1 day to 6 months.

10. (Once Amended) The [hydrogel biomedical article] microparticle of claim 1, wherein the [hydrogel] microparticle is biodegradable.

11. (Once Amended) The [hydrogel biomedical article] microparticle of claim 1, further comprising a contrast agent.

12. (Once Amended) The [hydrogel biomedical article] microparticle of claim 1, wherein the crosslinkable groups are crosslinked via free radical polymerization.

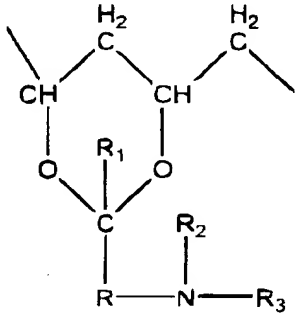
13. (Once Amended) The [hydrogel biomedical article] microparticle of claim 11, wherein the free radical polymerization is redox initiated.

Claims 14- 38. (Cancelled)

39. (New Claim) A hydrogel biomedical article formed from macromers having a polymeric backbone comprising units having a 1,2-diol or 1,3-diol structure and at least two pendant chains bearing crosslinkable groups, wherein the crosslinkable groups are crosslinked via redox initiated free radical polymerization.

40. (New Claim) The hydrogel biomedical article of claim 39, wherein the backbone polymer comprises poly(vinyl alcohol) (PVA) and copolymers thereof.

41. (New Claim) The hydrogel biomedical article of claim 39, wherein the macromer has the formula:



in which R is a linear or branched C_1-C_8 alkylene or a linear or branched C_1-C_{12} alkane; R_1 is hydrogen, a C_1-C_6 alkyl, or a cycloalkyl; R_2 is hydrogen or a C_1-C_6 alkyl; and R_3 is an olefinically unsaturated electron attracting copolymerizable radical having up to 25 carbon atoms.

42. (New Claim) The hydrogel biomedical article of claim 39, further comprising an active agent.

43. (New Claim) The hydrogel biomedical article of claim 42, wherein the hydrogel releases the active agent over a period of time ranging from about 1 day to 6 months.

44. (New Claim) The hydrogel biomedical article of claim 39, wherein the hydrogel is biodegradable.

45. (New Claim) The hydrogel biomedical article of claim 39, further comprising a contrast agent.

46. (New Claim) The hydrogel biomedical article of claim 39, wherein the article is selected from the group consisting of a catheter, tubing, vascular graft, heart valve, suture, prosthesis, dialysis membrane, filter, sensor, wound dressing, and drug delivery article.

47. (New Claim) The hydrogel biomedical article of claim 39, wherein the article is a microsphere.

48. (New Claim) The hydrogel biomedical article of claim 39, wherein the hydrogel is a coating.

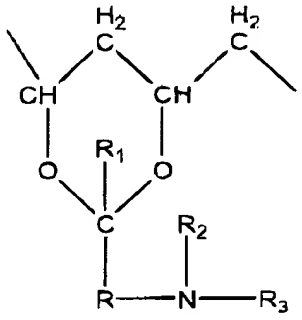
49. (New Claim) The hydrogel biomedical article of claim 39, wherein the article is formed in a mold.

50. (New Claim) The hydrogel biomedical article of claim 39, wherein the article is formed on a substrate.

51. (New Claim) A hydrogel biomedical article formed from macromers having a polymeric backbone comprising units having a 1,2-diol or 1,3-diol structure and at least two pendant chains bearing crosslinkable groups, wherein the article is biodegradable.

52. (New Claim) The hydrogel biomedical article of claim 51, wherein the backbone polymer comprises poly(vinyl alcohol) (PVA) and copolymers thereof.

53. (New Claim) The hydrogel biomedical article of claim 51, wherein the macromer has the formula:



in which R is a linear or branched C_1-C_8 alkylene or a linear or branched C_1-C_{12} alkane; R_1 is hydrogen, a C_1-C_6 alkyl, or a cycloalkyl; R_2 is hydrogen or a C_1-C_6 alkyl; and R_3 is an olefinically unsaturated electron attracting copolymerizable radical having up to 25 carbon atoms.

54. (New Claim) The hydrogel biomedical article of claim 51, further comprising an active agent.

55. (New Claim) The hydrogel biomedical article of claim 51, wherein the particle releases the active agent over a period of time ranging from about 1 day to 6 months.

56. (New Claim) The hydrogel biomedical article of claim 51, further comprising a contrast agent.

57. (New Claim) The hydrogel biomedical article of claim 51, wherein the article is selected from the group consisting of a catheter, tubing, vascular graft, heart valve, suture, prosthesis, dialysis membrane, filter, sensor, wound dressing, and drug delivery article.

58. (New Claim) The hydrogel biomedical article of claim 51, wherein the article is a microsphere.

59. (New Claim) The hydrogel biomedical article of claim 51, wherein the hydrogel is a coating.

60. (New Claim) The hydrogel biomedical article of claim 51, wherein the article is formed in a mold.

61. (New Claim) The hydrogel biomedical article of claim 51, wherein the article is formed on a substrate.